

From: Ex. 6 Personal Privacy (PP)
Sent: 10/16/2020 3:55:19 PM
To: Shams, Dahnish [Shams.Dahnish@epa.gov]; Thayer, Kris [thayer.kris@epa.gov]
Subject: STICS: Clearance Completion: #ORD-039047: External Peer Review for a Report on Physiologically Based Pharmacokinetic (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Parameter and Model Uncertainty: Introduction

The clearance for this product is complete:

- **Product type, subtype:** Presentations and Technical Summaries, Presentation
- **Product title:** External Peer Review for a Report on Physiologically Based Pharmacokinetic (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Parameter and Model Uncertainty: Introduction
- **Author(s):** Thayer, K
- **Initiator:** Dahnish Shams,ord/cphea/cpad
- **ORD Tracking Number:** Tracking # ORD-039047
- **Impact / Purpose Statement:** Presentation for public peer review meeting of the Chloroprene PBPK Model and Supplementary Uncertainty Analysis
- **Product Description / Abstract:** On June 26, 2017, the U.S. EPA received a Request for Correction (RFC) provided on behalf of Denka Performance Elastomer LLC (DPE). In the RFC letter, DPE states that the Toxicological Review of Chloroprene (CAS NO. 126-99-8) in Support of Summary Information on the Integrated Risk Information System (IRIS), disseminated by EPA's Office of Research and Development (ORD) in 2010, does not reflect the "best available science" or "sound and objective scientific practices" and requested correction. On January 25, 2018, EPA concluded in response that the underlying information and conclusions presented in the IRIS Chloroprene assessment are consistent with the EPA's Information Quality Guidelines and that no evidence published since the 2010 IRIS Assessment would change its conclusions. On July 23, 2018, DPE submitted a Request for Reconsideration of Denial of Request for Correction (RFR) with regards to EPA's decision and entered discussions with EPA to address the uncertainties identified by EPA as documented in the RFC response. More information regarding the Chloroprene RFC/RFR can be found on the EPA's Information Quality Guideline website. Discussions with Denka LLC and its contractor, Ramboll, are summarized on the IRIS website. An updated PBPK model is now available in a report: "Physiologically Based Pharmacokinetic (PBPK) Modeling for Chloroprene (Ramboll, 2020)." This report and the Supplemental Analysis of Metabolite Clearance (U.S. EPA, 2020) document will undergo external peer review to help to inform future decisions regarding the RFR.
- **Tracking and Planning 2019 Forward Field Set**
 - Research Area: N/A - Not Applicable N/A - Not Applicable
 - Product: N/A - Not Applicable
 - Product Description: N/A - Not Applicable
 - Topic(s):
 - N/A - Not Applicable
 - Research Program Area: N/A - Not Applicable
- **Product Category:** Does not require Advance Notification
- **Is there an approved QAPP (or QAPPs) supporting this product?:** Not Applicable

- **QAPP Reference:** N/A

- **Keywords:**

- IRIS
- Chloroprene
- Peer Review
- PBPK

- **Meeting Information:**

- Meeting Name: External Peer Review of a Report on Physiologically Based Pharmacokinetic (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance Meeting

- Meeting Start Date: 10/05/2020

- Meeting End Date: 10/06/2020

- **Published Date:** 10/05/2020

This submission can be found in the History tab. [Please click here to access STICS.](#)